



FORM PTO-1449/A and B (Modified)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/821,811	ATTY. DOCKET NO.: P0453.70115US01
FILING DATE: April 8, 2004	CONFIRMATION NO.: 8061
APPLICANT: Sanghvi et al.	
GROUP ART UNIT: 1614	EXAMINER: Not Yet Assigned

Sheet 1 of 3

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A30	4,311,833		Namikoshi, <i>et al.</i>	01-19-1982
	A31	4,377,568		Chopra, <i>et al.</i>	03-22-1983
	A32	4,385,078		Onda, <i>et al.</i>	05-24-1983
	A33	4,457,907		Porter, <i>et al.</i>	07-03-1984
	A34	4,462,839		McGinley, <i>et al.</i>	07-31-1984
	A35	4,518,433		McGinley, <i>et al.</i>	05-21-1985
	A36	4,556,552		Porter, <i>et al.</i>	12-03-1985
	A37	4,606,909		Bechgaard, <i>et al.</i>	08-19-1986
	A38	4,615,885		Nakagame, <i>et al.</i>	10-07-1986
	A39	4,670,287		Tsuji, <i>et al.</i>	06-02-1987
	A40	4,857,833		Sherman, <i>et al.</i>	08-15-1999
	A41	4,888,346		Bihari, <i>et al.</i>	12-19-1989
	A42	5,426,112		Zagon, <i>et al.</i>	06-20-1995
	A43	5,536,507		Abramowitz, <i>et al.</i>	07-16-1996
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	A49	5,626,875		Ballester Rodes, <i>et al.</i>	05-06-1997
	A50	5,629,001		Michael, <i>et al.</i>	05-13-1997
	A51	6,025,154		Li, <i>et al.</i>	02-15-2000
	A52	6,353,004	B1	Farrar, <i>et al.</i>	03-05-2002
	A53	6,469,030	B2	Farrer, <i>et al.</i>	10-22-2002
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**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B22	AU	758,416		Arch Development Corp.	07-03-1999	
	B23	CA	2,312,234		Arch Development Corp.	05-14-1999	
	B24	DE	3,780,819				
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.J./ (09/21/2008)

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**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C117	ALTIER et al., Opioid receptors in the ventral tegmental area contribute to stress-induced analgesia in the formalin test for tonic pain. Brain Res. 1996 Apr 29;718(1-2):203-6.	
	C118	BAKER et al., Functional effects of systemically administered agonists and antagonists of mu, delta, and kappa opioid receptor subtypes on body temperature in mice. J Pharmacol Exp Ther. 2002 Sep;302(3):1253-64.	
	C119	BASILISCO et al., Oral naloxone antagonizes loperamide-induced delay of orocecal transit. Dig Dis Sci. 1987 Aug;32(8):829-32.	
	C120	BASILISCO et al., Effect of loperamide and naloxone on mouth-to-caecum transit time evaluated by lactulose hydrogen breath test. Gut. 1985 Jul;26(7):700-3.	
	C121	BOWEN et al., Antagonism of the antinociceptive and discriminative stimulus effects of heroin and morphine by 3-methoxynaltrexone and naltrexone in rhesus monkeys. J Pharmacol Exp Ther. 2002 Jul;302(1):264-73.	
	C122	BOWEN et al., College on Problems of Drug Dependence 64th Annual Scientific Meeting. June 8-13, 2002. Quebec City, Quebec, Canada. Abstracts. Drug Alcohol Depend. 2002 May 1;66 Suppl 1:S1-220. Abstract No. 65.	
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	C124	CHOI et al., Opioid antagonists: a review of their role in palliative care, focusing on use in opioid-related constipation. J Pain Symptom Manage. 2002 Jul;24(1):71-90. Review.	
	C125	CHOI et al., Inhibition of chemokine-induced chemotaxis of monkey leukocytes by mu-opioid receptor agonists. In Vivo. 1999 Sep-Oct;13(5):389-96.	
	C126	DE PONTI et al., Methylnaltrexone Progenics. Curr Opin Investig Drugs. 2002 Apr;3(4):614-20. Review.	
	C127	FLORES et al., Mechanisms of morphine-induced immunosuppression: effect of acute morphine administration on lymphocyte trafficking. J Pharmacol Exp Ther. 1995 Mar;272(3):1246-51.	
	C128	GILES et al., Quaternary opiate antagonists lower blood pressure and inhibit leucine-enkephalin responses. Eur J Pharmacol. 1983 Nov 25;95(3-4):247-52.	
	C129	HO et al., Suppression of immunological functions in morphine addicted mice. NIDA Res Monogr. 1986;75:599-602.	
	C130	KEHLET et al., Review of postoperative ileus. Am J Surg. 2001 Nov;182(5A Suppl):3S-10S. Review.	
	C131	KOSTEN et al., Naltrexone and morphine alter the discrimination and plasma levels of ethanol. Behav Pharmacol. 1999 Feb;10(1):1-13.	
	C132	KOSTIC, CAS Abstract Document No. 127: 13345, 1997.	
	C133	LI et al., Methadone enhances human immunodeficiency virus infection of human immune cells. J Infect Dis. 2002 Jan 1;185(1):118-22. Epub 2001 Dec 14.	
	C134	MACK, Paralytic ileus: response to naloxone. Br J Surg. 1989 Oct;76(10):1101.	
	C135	NEMETH-LEFKOWITZ et al., Research communication in Substances of Abuse (1980) 1(2): 177-83.	
	C136	PHAM et al., Drugs of Abuse: Chemistry, Pharmacology, Immunology and AIDS; National Institute of Drug Research 96: Monograph Series. U.S. Department of Health and Human Services; 1990.	
	C137	QUANG-CONTAGREL et al., Long-term methadone treatment: effect on CD4+ lymphocyte counts and HIV-1 plasma RNA level in patients with HIV infection. Eur J Pain. 2001;5(4):415-20.	
	C138	SAKURADA et al., Differential antagonism of endomorphin-1 and endomorphin-2 supraspinal antinociception by naloxonazine and 3-methylnaltrexone. Peptides. 2002 May;23(5):895-901.	
	C139	SANDNER-KEISLING et al., Pharmacology of opioid inhibition to noxious uterine cervical distension. Anesthesiology. 2002 Oct;97(4):966-71.	
	C140	SHAVIT et al., Effects of a single administration of morphine or footshock stress on natural killer cell cytotoxicity. Brain Behav Immun. 1987 Dec;1(4):318-28.	
	C141	SOLDANI et al., Central and peripheral involvement of mu receptors in gastric secretory effects of opioids in the dog. Eur J Pharmacol. 1985 Nov 19;117(3):295-301.	
	C142	STEINBROOK et al., An opioid antagonist for postoperative ileus. N Engl J Med. 2001 Sep 27;345(13):988-9.	
	C143	WEI et al., Abstracts of the 2002 Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics. Atlanta, Georgia, USA. March 24-27, 2002. Clin Pharmacol Ther. 2002 Feb;71(2):P1-136.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /D.J./ (09/21/2008)

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	C144	WILMORE et al., Can we minimize the effects of opioids on the bowel and still achieve adequate pain control? Am J Surg. 2001 Nov;182(5A Suppl):1S-2S.		
	C145	WYBRAN et al., Suggestive evidence for receptors for morphine and methionine-enkephalin on normal human blood T lymphocytes. J Immunol. 1979 Sep;123(3):1068-70.		
	C146	YUAN, Clinical Status of Methylnaltrexone, A New Agent to Prevent and Manage Opioid-Induced Side Effects. J Support Oncol. 2004 Mar/Apr: 2(2):111-22.		

EXAMINE R /Donna Jagoe/	DATE CONSIDERED 9/21/2008
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an IDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]

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